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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/721,857

11/25/2003

Fred H. Burbank

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EXAMINER

HOUSTON, ELIZABETH

ART UNIT

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3731

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/721,857	<b>Applicant(s)</b> BURBANK ET AL.	
	<b>Examiner</b> ELIZABETH HOUSTON	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-18,21,22 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) 9,13,14 and 24-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,10-12,15-18,21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Species A (Figs. 1-5) in the reply filed on 11/18/07 is acknowledged.
2. Claims 9, 13, 14 and 24-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species or invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/18/07.

### *Claim Objections*

3. Claims 5, 6 and 8 are objected to because of the following informalities: inconsistency. Claims 5, 6 and 8 state the limitation "first occlusion element" while claim 1 from which they depend recite the limitation "first occluding element. Although it is clear that both terminologies refer to the same element, it is requested that the claims be amended to maintain consistency throughout. Appropriate correction is required.
4. Claim 21 objected to because of the following informalities: Claim 21 is dependent from a cancelled claim. For the purposes of this action, the claim will be treated as dependent from the most previous independent claim which in this case is claim 1. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 8, 12 and 15-18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 8 recites the limitation "the occlusion element" and "the distal shaft section". Since claim 1 from which claim 8 depends recites both a first occluding element and second occluding element, it is unclear which occluding element claim 8 is referring to. Since claim 1 from which claim 8 depends recites both a first distal shaft section and a second distal shaft section, it is unclear which distal shaft section claim 8 is referring to. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 12 recites the limitation "the occlusion element" and "the distal shaft section". Claim 1 recites both a first distal shaft section and a second distal shaft section and so it is unclear which distal shaft section claim 12 is referring to. There is insufficient antecedent basis for this limitation in the claim.

9. Claims 15-18 recites the limitation "the blood flow sensor" and "the Doppler crystal". There is insufficient antecedent basis for this limitation in the claim since these claims depend from claim 1.

10. Claims 21 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Claims 21 and 22 recite that the “occluding member” is distally extended. However claim 1 recites that the occluding member includes the proximal shaft the distal shaft and the occluding element that extends at from the distal shaft. It is therefore unclear whether how the occluding member can be extended away from the distal shaft when the occluding member includes the distal shaft.

### ***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**12. Claims 1-6 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Schifano (US 5,591,173).**

13. Schifano discloses the invention substantially as claimed including a first occluding member which has a first elongated shaft, which has a first operative proximal shaft section configured to extend out of the patient during treatment (11; fig. 1), which has a first distal shaft section with a first pressure applying occluding element (15) secured to the first-distal shaft section and which has a first mechanism (22) to extend at least part of the occluding member from a first position distally (Fig. 5) to a second position away from the first distal shaft section (Fig. 4 or 2 where the occluding member is in a position away from the distal shaft section compared to its position in Fig. 5); a

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second occluding member which has a second elongated shaft, which has a second operative proximal shaft section configured to extend out of the patient during treatment (12) and which has a second distal shaft section with a second pressure applying occluding element (15) secured to the second distal shaft section; and a connection (13) between the first and second occluding members which is configured to adjust spacing between the first and second occluding elements to press the pressure applying elements against the patient's vaginal wall to occlude underlying uterine arteries. Schifano discloses the second occluding member has a second mechanism (22) to adjust the orientation or the location of at least part of the second occluding element with respect to the second distal shaft section (compare figs. 4 and 5). The connection between the first and second occluding members is a pivotal connection (13). Each of the proximal shaft sections of the occluding members includes a finger engaging grip (14). At least part of the first occlusion element is configured for positional adjustment in-line with the distal shaft section (Figs. 2 and 4). At least part of the first occlusion element is configured for rotation within a plane at or near the distal shaft section (the whole device is capable of being rotated and therefore the occlusion elements are capable of being rotated). The occluding element includes an occlusion bar with a pressure applying surface (16, 17), and that the occlusion bar has a pair of legs which extend from a surface opposite to the pressure applying surface (portion surrounded by spring). The distal shaft section (which includes 26 and 27) has a pair of arms (24, extending from 26) with recesses configured to receive the legs (see Fig. 1 or 4).

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**15. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schifano (US 5,591,173) in view of Malecki (US 6,368,340).**

16. Schifano discloses the invention substantially as claimed as stated above including a mechanism (22) that extends the occlusion element distally away from the distal shaft section (Fig. 2 or 4).

17. Schifano does not disclose that the mechanism for extending the occlusion element is effected by fluid under pressure.

18. Malecki discloses a clamp assembly that utilizes a hydraulic actuator for moving the occlusion element (C 20: L28-53). Malecki states that the use of a hydraulic system is an advantage because it does not take up much room in a trocar sleeve and enhances visualization (C 18: L 55-60).

It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a hydraulic system in place of the biasing springs into the invention of Schifano. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded

predictable results to one of ordinary skill in the art at the time of the invention.

Furthermore, the hydraulic system is an enhancement over the mechanism used by Schifano for the reasons taught by Malecki and stated above.

**19. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schifano (US 5,591,173).**

20. Schifano fails to particularly disclose that the occluding member is displaced a distance of up to about one inch of between 0.25 to 0.8 inch from the distal shaft section. However, it would have been obvious to displace the occluding member a varied distance of up to about one inch or between 0.25 to 0.8 inch from the distal shaft section in order to make the device of a sufficient size to be used to occlude uterine arteries. See *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

**21. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schifano (5,591,173) in view of Hossack et al (US 6,045,508).**

38. Schifano discloses the invention substantially as claimed above but fails to disclose a blood flow sensor.

22. However, Hossack teaches a Doppler crystal mounted in the surface of a device meant to be placed within the body (col. 3, lines 35-37 and col. 4, lines 49-51).

Therefore it would have been obvious to add the Doppler crystal of Hossack to the occlusion device of Schifano, in order to determine when the blood flow has been



successfully occluded. It is also old and well-known in the art to have blood flow sensors in occlusion devices. Additionally, it would have been obvious to position the Doppler crystal so that it has a direction of view away from the pressure applying surface of the occluding element, so that the blood flow in the artery adjacent to the portion that is occluded can be measured.

### ***Response to Arguments***

23. Applicant's arguments filed 11/18/07 have been fully considered but they are not persuasive. Regarding the Schifano reference, applicant states that the movement of the pressure applying elements is not "distal to the distal end of the distal shaft sections". However it is noted that these features upon which applicant relies are not recited in the rejected claim(s) in the way that applicant intends. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims require that the occluding element extends "from a first position distally" (without a claimed reference point) as in Fig. 5 of Schifano "to a second position away from the distal shaft section", as in figs. 2 or 4.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731